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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,207	01/16/2001	Iris Pecker	00/21505	1817

7590 11/25/2002

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EXAMINER	
DECLOUX, AMY M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/759,207	PECKER ET AL.	
	Examiner	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 September 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 7-9-02, (Paper No. 12) and on 9-3-02 (Paper No. 20) have been entered.

In view of Applicant's Amendments filed on 7-9-02, (Paper No. 12) and on 9-3-02 (Paper No. 20), the outstanding rejection has been withdrawn. However, a new ground of rejection has been applied.

Interview

Applicant contends that in the interview held 4-18-02, that amending the two independent claims 1 and 6 to substitute "being at least 90% homologous to SEQ ID NO:2" for the previous language of "being at least 95% similar to SEQ ID NO:2" would render the claims allowable. The examiner respectively disagrees and points to the interview summary mailed 5-8-02, which states that such an amendment was discussed, but does not state that it was necessarily allowable. The discussion centered on how Applicant was to overcome the outstanding 112 first written description rejection which was based on a lack of support for the phrase "being at least 95% similar to SEQ ID NO:2" recited in the base claims at that point in time. Applicant said there was support for the phrase "being at least 90% homologous to SEQ ID NO:2" in Patent 5,968,822, and the examiner agreed to consider this latter phrase.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A) Claims 1-10 are not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation of an isolated antibody specifically binding at least one epitope of a mammalian heparanase protein, said heparanase protein being "at least 90% homologous to SEQ ID NO:2". There is no written

description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes new matter.

Applicant points for support for said phrase as being found in Column 6, lines 55-61 of Patent 5,968,822 (Patent Application Serial No. 08/922,170) from which the instant application claims priority. The examiner notes that said lines describe a polynucleotide sequence which encodes a polypeptide having heparanase activity which most preferably shares at least 90% homology with SEQ ID NO:10, and does not describe an antibody against a polypeptide having heparanase activity which most preferably shares at least 90% homology with SEQ ID NO:10. (SEQ ID NO:10 of '822 is identical to the instant SEQ ID NO:2.)

B) Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims are drawn to an isolated antibody specifically binding at least one epitope of a mammalian heparanase protein, said heparanase protein being "at least 90% homologous to SEQ ID NO:2". The instant specification discloses an antibody to a protein comprising SEQ ID NO:2, and states that said antibody can be used as a diagnostic tool for the quantitative determination of heparanase concentrations in biological fluids (see page 63 of the instant specification). However the instant claims encompass proteins with up to 10% of the residues being changed relative to SEQ ID NO:2, by virtue of being 90% homologous to the 500+ amino acid sequence of SEQ ID NO:2.

The predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar functions and properties requires a knowledge of, and guidance with regard to which amino acids in the amino acid sequence, if any are tolerant of modification and which are conserved (IE., expectedly intolerant to modification), and detailed knowledge of the ways in which the product's structure relates to its functional usefulness. For example a C282Y mutation in the HFE protein causes profound changes in the regulation of iron homeostasis in humans (Zhou et al PNAS (1998) 95:2492-7, see entire article, especially the abstract). Therefore, the problem of predicting functional aspects of the polypeptide product from mere sequence data of polypeptides being "at least 90% homologous to SEQ ID NO:2" and what changes can be tolerated is complex and well outside the realm of routine experimentation.

Therefore, these residue changes may alter the heparanase function of a polypeptide homologous to SEQ ID NO:2 . It is noted that though the specification teaches a function for antibodies which bind a protein comprising the amino acid sequence of SEQ ID NO:2, as discussed supra, the instant specification does not disclose a function for any other antibodies, including antibodies to proteins other than a heparanase comprising an amino acid sequence of SEQ ID NO:2. Therefore one of skill would not know how to use the breadth of the antibodies encompassed by the instant claims. Adding the limitation that said antibodies would still be able to bind at least one epitope of a protein set forth in SEQ ID NO:2 would be one way to overcome this rejection, provided there is support in the specification.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are indefinite in the recitation of an isolated antibody specifically binding at least one epitope of a mammalian heparanase protein, said heparanase protein being "at least 90% homologous to SEQ ID NO:2", because the instant specification does not disclose how 90% homology is determined.

It is noted that applicant states that the software used for sequence homology determination is disclosed at column 16, lines 17-22 of U.S. Patent No. 5,968,822. However the algorithm used to determine 90% homology is not clear. Applicant is requested to clarify.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,177,545. Although the

conflicting claims are not identical, they are not patentably distinct from each other because of the scope of the pending claims which encompass the species of the patented claims. The pending claims encompass antibodies to proteins being at least 90% homologous to SEQ ID NO:2, while the patented claims, which are directed to antibodies to a protein having an amino acid sequence as set forth in SEQ ID NO:2. The limitations recited in the dependent claims are essentially identical in both sets of claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
November 21, 2002

Patrick J. Nolan, Ph.D.,
Primary Patent Examiner,
Group 1640